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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/744,146 | 03/29/2001 | Masayuki Machida | 10287.39 | 3956 |
| 27683 | 7590 | 11/04/2003 | EXAMINER | |
| HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202 | | | SISSON, BRADLEY L | |
| | | | ART UNIT | PAPER NUMBER |

1634

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/744,146 | MACHIDA ET AL. | |
| | Examiner | Art Unit | |
| | Bradley L. Sisson | 1634 | |

-- *Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a “written description of the invention” which is separate and distinct from the enablement requirement. The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the “applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

2. The amendment received 10 July 2003 introduced new matter into each of the three independent claims, claims 35-37, from which claims 8-11 depend. While pages 6-7 of the response of 10 July 2003 (hereinafter the response) directs attention to where support can be found, a careful review of the citations fails to produce the requisite support.

3. The following passage is taken from page 6 of the response, which is directed to providing support for language found in Claim 35, and seemingly by extension, claims 36-37.

“a number of target receptors of length up to 1mm, each receptor having a first end and a second end” has support at page 7, lines 18-24; page 5, lines 11-13, and claims as originally filed;

4. A review of the specification fails to find any support for where “target receptors” have a length of “up to 1 mm.” The specification does provide support for solid supports, e.g., particles, that have a diameter of 1 mm, but no length of any target receptor (i.e., DNA), in terms of mm is provided. New claims 36 and 37 suffer equally from not having support for this limitation.

5. Page 6 of the response also asserts the following clause has support in the specification:

“wherein said target receptors are single-stranded nucleic acids of predetermined base sequence” has support at page 11, lines 12-13;

A review of said page 11, lines 12-13, fails to find support for single-stranded target receptors of a predetermined base sequence. For convenience, said page 11, lines 12-13 are reproduced below.

the invention through to the fifth aspect of the invention, the target receptor is a single strand nucleic acid. Here, it is possible to obtain a single strand, for

While it is clear that the cited passage does provide support for the target receptor being “single stranded,” such does not support the limitation that it be of a “predetermined base sequence.”

6. Page 6 of the response also asserts that the limitation of “forming a labeled complex having a predetermined molar ratio of the labeled substances” is supported by at page 25, lines 1-3. For convenience, the noted citation is reproduced below.

25

~~In FIG. 1 (a), a case where the molar ratio of the fluorescent substance 13 and the fluorescent substance 15 is, for example, 4 to 1 as a whole is illustrated with five target receptors 12 for simplicity of description. On the~~

In the event that applicant was referring to the substituted first paragraph for page 25, the first three lines of the amended paragraph, are reproduced below.

Page 25, paragraph 1:

In FIG. 1 (a), a case where the molar ratio of the fluorescent substance 13 and the fluorescent substance 15 is, for example, 4 to 1 as a whole is illustrated with five target receptors 12 for simplicity of description. On the other hand, the labeled composite particle 16

As can be seen above, neither version offers support for the formation of “a labeled complex having a predetermined molar ratio of the labeled substances.”

7. Page 6, last paragraph, bridging to page 7, of the response is reproduced below:

“wherein the number and length of target receptors bonded to said carrier particle is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby

enhancing discrimination by stable emission” has support at page 6, lines 17-23; page 8, lines 16-21, and page 28, lines 14-19.

A review of the cited passages fails to provide support for the concepts of “number and length of target receptors...” For convenience, the cited passages are reproduced below:\

Page 6, lines 17-23:

16
17
18 (2) By bonding a labeled substance with a target receptor, compared with
the case where the labeled substance is attached directly to a carrier such as a
micro particle and the like, the space and distance between labeled substances
20 are expanded, energy movement between the labeled substances and
occurrence of quenching are prevented, and the possibility of discrimination by
stable emission and the like can be guaranteed more reliably even if a lot of
labeled substances are held by the carrier.

Page 8, lines 16-21:

19
20
21
22 particle and the like. Consequently, the space between the labeled substances
can be larger than in the case where substances are bonded directly with the
carrier, so that interactions such as energy movement between labeled
substances and quenching (in the case where a luminescent material is used)
20 are prevented. Therefore, it is possible to discriminate many substances
consistently and with high accuracy.

Art Unit: 1634

Page 28, lines 14-19:

11 The number of target receptors 12 to be bonded with the micro particles
115 11 can be controlled by changing the number of target receptors 12 or
12 conditions of reaction time and the like. By increasing the number within the
13 range where a major influence by energy movement or quenching does not
14 occur among the fluorescent substances, emission intensity and capture ability
15 can be enhanced.

A review of the cited passages is considered to produce support for the number and spacing of labeled substances on a receptor; however, said citations do not provide support for altering the length of the target receptor.

8. In view of the amendments to the claims, and the lack of support for the new limitations, claims 8-11 and 35-37 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1634

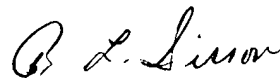
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 2, 2003